KP1077

KP1077 is the lead prodrug candidate in Zevra's Rare Sleep Disorders Program for Idiopathic Hypersomnia (IH) and Narcolepsy Type I & II

KP1077 for IH was granted Orphan Drug Designation by the US Food & Drug Administration (FDA) and is currently in Phase 2 clinical trials.

An investigational new drug (IND) application was opened in April 2023 to begin clinical trials for KP1077 in narcolepsy. There is a potential to advance KP1077 for expedited approval pathways.

WHAT IS KP1077?

Serdexmethylphenidate (SDX) is the sole active pharmaceutical ingredient in KP1077. SDX is a prodrug of dextemethylphenidate (d-MPH) - a central nervous system stimulant.

• By design, SDX does not exhibit pharmacological effects until metabolized to active d-MPH.
• Individual titration to an optimal SDX dose has the potential to improve effectiveness, in treating rare sleep disorders, such as IH and Narcolepsy.

WHAT IS IDIOPATHIC HYPERSOMNIA (IH)?

• IH is a rare, neurological sleep disorder that causes excessive daytime sleepiness.
• People with IH experience daytime lapses into sleep, or an irrepressible or uncontrollable need to sleep that persists even with adequate or prolonged nighttime sleep.
• Additionally, IH can cause “sleep inertia” resulting in extreme difficulty waking, and unintentionally falling asleep or falling asleep at inappropriate times.
• Another symptom of IH can be “brain fog” - characterized by, for example, impaired ability to focus, memory lapses and lack of mental clarity that in severe cases can lead to depression.

Supported prevalence estimates show that IH occurs in approximately 10 of every 100,000 people.